RxGPS supports the adoption and implementation of effective serialization requirements as one tool to secure the legitimate supply chain. Despite the ultimate value of serialization, up-front investments are significant and the implementation process can be operationally and technologically challenging and can vary among manufacturers, plants, and packaging lines. As has been seen in several markets, unreasonably fast implementation timelines result in delays, confusion, and wasted investment of resources. An appropriately phased implementation process that follows the principles outlined in this document helps both industry and regulators develop effective systems and processes to realize the maximum benefit of serialization.

The following are critical to an effective implementation process for serialization requirements:

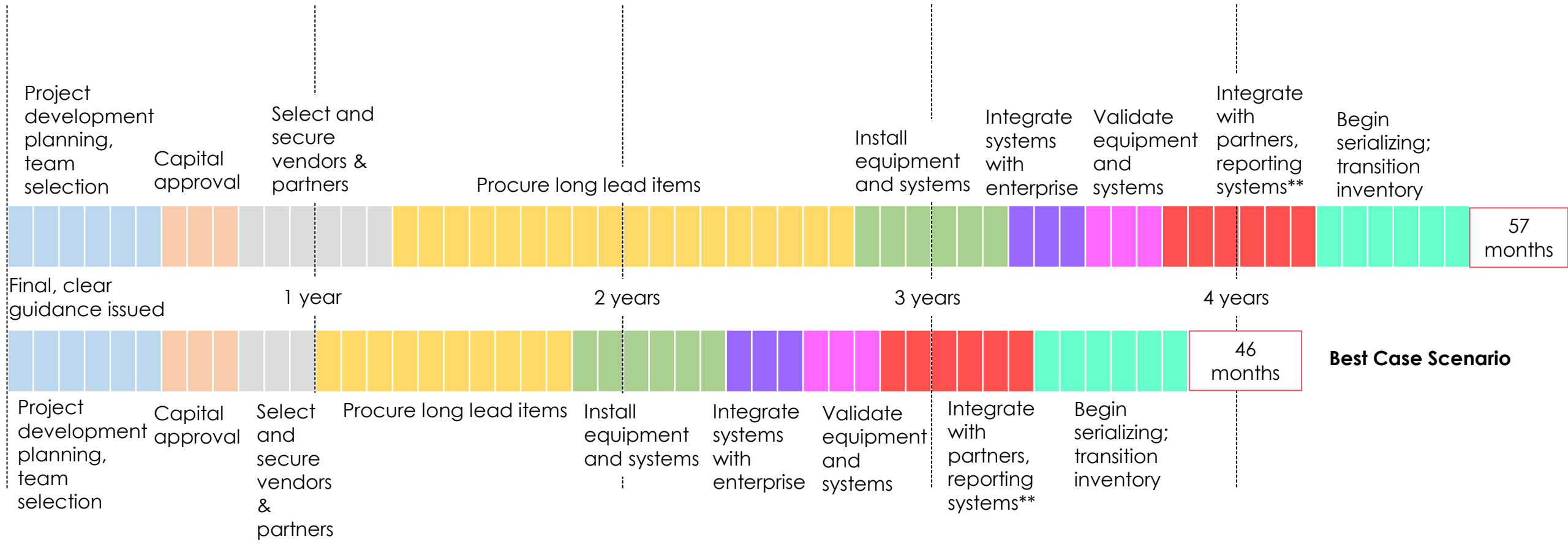
1. **Global data standards should be used.** The use of non-standard approaches can add years to implementation because new systems must be developed and learnings from other markets cannot be leveraged. The complexity of non-standard approaches also adds significant cost to implementation and the health care system.
2. **All compliance deadlines should be based on the date of publication of final, clear guidance.** Industry cannot begin implementation until a complete and final set of requirements is available. Additionally, any change in scope from a previously published law, regulation, or guidance will impact the implementation process. Changes in scope should be (1) written and published through formal law, regulation, or guidance and (2) provide additional implementation time to account for the change in scope.
3. **Serialization should be phased in over time in a manner that provides flexibility to manufacturers. A single compliance date should not be used for all requirements for all products.** Each manufacturer has its own strategy for where and how it packages its products, and similarly, each manufacturer will have its own strategy for how it updates its packaging lines to comply with new serialization requirements. Serialization requirements should be staged in a manner that recognizes these important business implications. Specifically, we believe serialization should be phased in over multiple years with each manufacturer required to serialize a set percentage of its product during the first year after the compliance data, serialize an additional percentage the following year, and so forth.[1] This approach is preferable to an approach in which the regulator identifies the types of products to be serialized in each year because such

[1] With this approach, downstream trading partners, such as wholesalers, must be able to assume manufacturers have properly chosen to serialize or not serialize a particular product during the transition period.

requirements can have a disproportionate and unfair impact among manufacturers with different product mixes.

4. **Verification of serialized saleable units should be achieved first. Any additional requirements should be phased in over time and only after verification capabilities are in place.** Without verification and decommissioning of saleable units prior to dispensing to patients, safety of the supply chain may be compromised. More elaborate requirements provide modest additional value, increase the complexity and time for implementation, and should not be considered until the benefit of verification and decommissioning have been realized.
5. **The first serialization requirements (*i.e.*, affixing a unique identifier to packages) should not be effective until at least four years after publication of final, clear guidance.** A number of decisions and processes are required to fully implement serialization on a packaging line. The timelines below explain why at least four years is needed for a manufacturer to first serialize products. Additionally, the dramatic increase in serialization requirements around the world is significantly constraining the availability of necessary equipment and resources in any individual market. Downstream verification activities (*e.g.*, scanning product) that make use of serialization can take significantly longer than four years.

Implementation Timeline for Manufacturer Serialization of Salable Units*



* This timeline assumes the use of global standards; because no markets require serialization of the primary package, this timeline assumes that serialization is occurring at the salable unit level. The timeline would be much longer in the case of primary package serialization.
** This assumes that external connections for reporting systems are finalized.